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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,546	10/10/2003	K. M. Slimak	TPP 31413DIV	9719

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EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/682,546	SLIMAK, K. M.	
	Examiner	Art Unit	
	Randall Winston	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-19* is/are pending in the application.

4a) Of the above claim(s) *15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-14 and 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/889,133.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0905*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the election of species requirement in its response of 09/28/2005 of a) aroid b) seizures c) non-verbal austistic child is acknowledged. The traversal is based on the grounds that applicant argues that it appears that a search of the subject matter of the elected invention would, of necessity, overlap the search area of the non-elected invention. Furthermore, applicant argues MPEP 803 "If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions."

Applicant's argument is not found persuasive because, applicant did not demonstrate that the species are not patentably distinct and applicant did not submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

The election of species requirement is still deemed proper and is therefore made final.

Claims 15 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Readable claims 1-7, 9-14 and 17-19 will examined on the merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created

doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 9-14 and 17-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,632,461.

Although the conflicting claims are not identical, they are not patentably distinct from each other because in both cases, the claims are drawn to a method of treating chronic diseases, conditions and symptoms in animal, including humans comprising: a) withholding all food for at least 5 days, except for tropical root crops; and b) feeding a concentrated form of tropical root crops for at least the five day period.

Further, the instantly claimed invention encompasses the claimed invention of 6,632,461.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-14 and 17-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for a method of treating particular conditions and symptoms in animals, including humans (i.e. Applicant is enabled for treating the particular conditions and symptoms recited in claim 1 of Application No. 09/889,133 issued as U.S. Patent No. 6,632,461. Also please note Application 10/682,546 being a divisional of parent application 09/889,133) selected from the group consisting of autism, anxiety, arthritis, asthma, colic, congestion, diabetes, digestive upsets, irritable bowel syndrome, eczema, fatigue, migraine headaches, multiple sclerosis, seizures and rashes comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of tropical root crops selected from the group consisting of white sweet potato, malanga, cassava, true yam, water chestnut, arrowroot, and lotus for a period of at least five days to said patient (as recited in claim 1 of US 6,632,461), the specification does not enable any person in the art in preparing a method of treating any and/or all chronic diseases, conditions and symptoms in animals, comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient.

The factors to be considered in determining whether undue experimentation is required are summarized in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; © the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the

art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a method of treating any and/or all chronic diseases, conditions and symptoms in animals, comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient. Applicant has reasonably demonstrated on pages 51-54, examples III-VI of the specification, a method of treating particular conditions and symptoms in animals, including humans (i.e. those recited in claim 1 of Application No. 09/889,133 issued as U.S. Patent No. 6,632,461) selected from the group consisting of autism, anxiety, arthritis, asthma, colic, congestion, diabetes, digestive upsets, irritable bowel syndrome, eczema, fatigue, migraine headaches, multiple sclerosis, seizures and rashes comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of tropical root crops selected from the group consisting of white sweet potato, malanga, cassava, true yam, water chestnut, arrowroot, and lotus for a period of at least five days to said patient (as recited in claim 1 of US 6,632,461). Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a method of treating any and/or all chronic diseases, conditions and symptoms in animals, comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient.

Moreover, it should be noted that the state of the prior art at the time the invention was filed did not recognize a method of treating any and/or all chronic diseases, conditions and symptoms in animals via any method including the method instantly claimed. For example, Slimak et al. et al. teach (US 5789012 see, e.g. title, column 2, lines 33-35) feeding tropical root crops selected from the group consisting of sweet potatoes, cassava, edible aroids, amaranth, yams lotus and potatoes to treat conditions such as food allergies. Thus, the art is silent regarding the efficacy of applicant's method of treating any and/or all chronic diseases, conditions and symptoms in animals, comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient. Therefore, applicant's claimed method is highly unpredictable in the art. In addition, the applicant's specification fails to provide guidance or working examples whereby applicant prepares a method of treating any and/or all chronic diseases, conditions and symptoms in animals, comprising a) withholding all food for at least 5 days, except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days to said patient.

Therefore, it would require undue experimentation without a reasonable expectation of success for one of skill in the art to practice the invention commensurate in scope with the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTOPHER R. TATE
PRIMARY EXAMINER